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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,956	06/08/2005	William T McAllister	R1401-100-US	1385
23550	7590	12/13/2007		
HOFFMAN WARNICK & D'ALESSANDRO, LLC			EXAMINER	
75 STATE STREET			KIM, YOUNG J	
14TH FLOOR			ART UNIT	PAPER NUMBER
ALBANY, NY 12207			1637	
			NOTIFICATION DATE	DELIVERY MODE
			12/13/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOCommunications@hwdpatents.com

**Office Action Summary**

Application No.

10/537,956

Applicant(s)

MCALLISTER ET AL.

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 8-17 is/are pending in the application.
- 4a) Of the above claim(s) 5,6 and 8-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 16 and 17 is/are rejected.
- 7) ☒ Claim(s) 2-4, 16 and 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

The present Office Action is responsive to the Amendment received on September 27, 2007.

#### ***Preliminary Remark***

The Examiner of record has been changed.

All future correspondence should be addressed to Young J. Kim, in the Group Art Unit 1637.

Claim 7 is canceled.

#### ***Election/Restrictions***

This application contains claims 5, 6, and 8-15, drawn to non-elected invention, non-elected without traverse, in the response received on February 13, 2007.

#### ***Claim Objections***

Claims 2-4, 16, and 17 are objected to for being a duplicate of claim 1.

Claim 1 is drawn to a product, said product being an enzyme comprising SP6 RNA polymerase having a deletion of residues 140 through 143.

The specification appears to indicate that this deletion is responsible for the characteristics which are recited in claims 2-4, 16, and 17. However, whether such characteristics are recited in a claim or not, if the enzyme comprises the deletion responsible for the purported characteristics, then claims 2-4, 16, and 17 do not further limit the enzyme of claim 1.

#### ***Claim Rejections - 35 USC § 112 – Necessitated by Amendment***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-4, 16, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to an improved bacteriophage RNA polymerase enzyme "comprising a bacteriophage SP6 RNA polymerase having a deletion of residues 140 through 143...."

It is unclear how an enzyme can comprise another enzyme.

Amending the claim to recite that the improved bacteriophage RNA polymerase enzyme is a bacteriophage SP6 RNA polymerase having a deletion of residues 140 through 143 would overcome the rejection.

Claims 2-4, 16, and 17 are indefinite by way of their dependency on claim 1.

***Claim Rejections - 35 USC § 112 – Written Description***

The rejection of claims 1-4, 16 and 17 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, made in the Office Action mailed on April 17, 2007 is withdrawn in view of the Amendment received on September 27, 2007.

***Claim Rejections - 35 USC § 102***

The rejection of claim 4 under 35 U.S.C. 102(e) as being anticipated by Watahiki et al (U.S. 2004/0259089), made in the Office Action mailed on April 17, 2007 is withdrawn in view of the Amendment received on September 27, 2007, canceling the rejected claim.

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The rejection of claims 1-4, 16 and 17 under 35 U.S.C. 102(b) as being anticipated by Lyakhov et al (J. Mol. Biol. (1997) 269:28-40), made in the Office Action mailed on April 17, 2007 is withdrawn in view of the Amendment received on September 27, 2007. Specifically, Applicants' declaration that the invention directed to T3 RNA polymerase comprising deletions at 174-174 position appears to be supported by the evidence provided by Applicants on page 9 of the document having the date of January 27, 1997, which sufficiently antedates the publication date of Lyakhov et al.

***Maintained***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 1-4, 16 and 17 under 35 U.S.C. 102(e) as being anticipated by Watahiki et al (U.S. 2004/0259089), made in the Office Action mailed on April 17, 2007 is maintained for the reasons already of record.

The rejection is maintained to the extent of the elected invention for prosecution. In other words, the claims under prosecution are drawn to (as amended) an RNA polymerase comprising a bacteriophage SP6 RNA polymerase having a deletion of residues of 140 through 143.

Applicants' arguments presented in the Amendment received on September 27, 2007 have been fully considered but they are not found persuasive for the reasons set forth in the, "Response to Arguments" section.

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The Rejection:

Watahiki teaches a mutant SP6 RNA polymerase with nucleotides 140-143 deleted (see paragraph 0069). Watahiki also teaches the T7 RNA polymerase with the 172-173 deletion (see paragraph 0072) and the T3 RNA polymerase with the deletion at 173-174 (see paragraph 0064).

With regard to claims 1-4, 16 and 17, since Watahiki teaches an RNA polymerase that is identical in structure to the RNA polymerase being claimed (see paragraph 0069, for example), Watahiki inherently anticipates these claims.

Watahiki teaches a mutant SP6 RNA polymerase with nucleotides 140-143 deleted (see paragraph 0069).

Response to Arguments:

Applicants traverse this rejection.

Applicants refer to the declaration submitted under 37 CFR 1.31, declaring that prior to February 7, 1997, Applicants had conceived of the claimed invention, and in support of this declaration, provide New Technology Disclosure received by the Technology Transfer Office of the Research Foundation of the State University of New York on February 10, 1997, and a Letter to Dr. Albert E. Muir dated, February 5, 1997 (page 8, bottom paragraph, Response).

The declaration and the evidences were carefully reviewed.

However, the present examiner cannot find any reference or evidence which supports that fact that Applicants had conceived an SP6 RNA polymerase having deletions at 140-143. All of the evidences appear to reference to Applicants discovery of the T7 RNA polymerase deletion mutants (see "Brief Technical confidential description," element 9 of the Tech Disclosure statement). The Applicants' referenced letter to Dr. Muir also contains discussions directed toward T7 RNA polymerase, but fails to mention any information regarding SP6 RNA polymerase comprising the

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140-143 deletion. Lastly, the document dated January 27, 1997 also fails to disclose any reference to SP6 RNA polymerase comprising the required deletions so as to merit Applicants' assertion that the invention as claimed was conceived prior to the date purported by the Applicants.

Therefore, the rejection is maintained for the reasons of record.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot


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guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Young J. Kim  
Primary Examiner  
Art Unit 1637  
12/5/2007

YOUNG J. KIM  
PRIMARY EXAMINER

YJK